

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 35

UNITED STATES PATENT AND TRADEMARK OFFICE

---

BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

---

Ex parte CHARLES EBERT,  
GERARD C. MAZZENGA,  
JOHN H. OTTE, and  
BRET BERNER

---

Appeal No. 94-2894  
Application 07/725,222<sup>1</sup>

---

ON BRIEF

---

Before WINTERS and WILLIAM F. SMITH, Administrative Patent Judges, and  
McKELVEY, Senior Administrative Patent Judge.

WILLIAM F. SMITH, Administrative Patent Judge.

---

<sup>1</sup> Application for patent filed June 26, 1991. According to appellants, the application is a continuation of Application 07/638,944, filed January 9, 1991, now abandoned; which is a continuation of Application 07/512,639, filed April 20, 1990, now U.S. Patent No. 5,064,654; which is a continuation of Application 07/296,910, filed January 11, 1989, now abandoned; which is a continuation of Application 07/133,681, filed December 16, 1987, now abandoned.

Appeal No. 94-2894  
Application 07/725,222

### DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 2, 5 through 7, and 9 through 15, all the claims remaining in the application.

Claims 10, 15, and 7 are illustrative of the subject matter on appeal and read as follows:

10. A dosage form for transdermally administering a pharmaceutically active agent which dosage form comprises

- a) an impermeable backing,
- b) a rate-controlling membrane of polyurethane or ethylene-vinyl acetate of greater than 20% vinyl acetate and from 0.5 to 10.0 mils thick,
- c) a silicone-based or acrylic-based pressure sensitive adhesive on said rate controlling membrane distal from said backing,
- d) a reservoir formed by a and b,
- e) an aqueous pharmaceutically acceptable lower alkanol reservoir composition having a volume fraction of said lower alkanol of from 0.39 to 0.9 calculated based on said alkanol and water only, and
- f) said pharmaceutically active agent.

15. A transdermal drug delivery system comprising

- (i) an occlusive, impermeable polymeric backing layer;
- (ii) a drug depot on one side thereof;
- (iii) a removable, occlusive covering layer over said drug depot; and
- (iv) an adhesive means by which said delivery system, absent said removable covering layer may be affixed to an intended patient;

said drug depot containing a drug formulation comprising a transdermally administrable pharmaceutically acceptable pharmaceutically active agent or a precursor thereof, water and lower alkanol;

said active agent or precursor thereof being present in a pharmaceutically effective amount;

said lower alkanol and said water being present in a volume:volume ratio of from 30:70 up to less than 95:5 such that said lower alkanol, water and drug are delivered to a patient's skin, which patient has applied said system absent said removable covering layer to said patient's skin, in amounts that said drug is delivered in a transdermally administrable efficacious amount, said water has an activity at said patient's skin of about 0.4 to about 0.95 and said lower alkanol, at said patient's skin, has an activity of 0.3 to about 0.9, and

wherein, once applied to said patient's skin, said lower alkanol has a flux from said system to said skin of at least 1500 mcg/cm<sup>2</sup>/hr and through said skin of at least 1500 mcg/cm<sup>2</sup>/hr.

7. The system of claim 15 wherein said water and said lower alkanol are delivered to said patient's skin so as to result in an ethanol activity of at least 0.5.

The examiner does not rely upon prior art references in rejecting the claims on appeal. Rather, claims 2, 5 through 7, and 9 through 15 are rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 1 through 11 of U.S. Patent No. 5,064,654 ('654 patent). In addition, claims 2, 5 through 7, and 9 through 15 stand rejected under 35 U.S.C. § 112, first and second paragraphs, as being nonenabled and indefinite. We reverse each of these rejections. In addition, we make new grounds of rejection under 37 CFR § 1.196(b) and statements under 37 CFR § 1.196(c).

### Double Patenting Rejection

This rejection is clearly erroneous. In relevant part, the claims on appeal require the presence of a "lower alkanol" while the claims of the '654 patent require the presence of "ethanol." The examiner's position as stated at page 2 of the Answer is "The instant claims are rejected under 35 USC § 101 based on Applicant's own specification wherein the only alkanol disclosed is ethanol."

It is difficult to discern why at this point in time an examiner would make such a rejection. The facts presented in this application are very similar to those presented in In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). In Vogel at 441, 164 USPQ at 622, the court stated:

A good test, and probably the only objective test, for "same invention," is whether one of the claims could be literally infringed without literally infringing the other. If it could be, the claims do not define identically the same invention.

Here, the present claims would be infringed by a device which uses methanol where such a methanol containing device would not infringe the claims of the '654 patent. Similar to the facts in Vogel, where the court determined that claims requiring pork are not identical to claims requiring meat, the claims in this application which require lower alkanol are not identical to the claims in the '654 patent which require ethanol.

The double patenting rejection is reversed.

Rejections Under 35 U.S.C. § 112, First and Second Paragraphs

The examiner considers the term "lower alkanol" as used in the claims on appeal to be indefinite and not enabled. The only reason given in support of the examiner's position is that the only lower alkanol exemplified in the specification of this application is ethanol. It appears to be the examiner's position that the claims on appeal must be limited to the presence of ethanol.

In regard to the rejection made under the first paragraph of this section of the statute, the examiner states at page 3 of the Examiner's Answer that "the claims are not commensurate in scope with that which is disclosed." This determination is clearly erroneous. The specification of this application clearly and unambiguously "discloses" that the present invention involves the use of lower alkanols. See, e.g., the paragraph bridging pages 4-5 of the specification. Suffice it to say that the examiner has failed to articulate any reason why one skilled in the art would not be able to make and use the claimed invention set forth in the claims on appeal.

Turning to the rejection as it is premised under the second paragraph of this section of the statute, the examiner's position as set forth at page 3 of the Examiner's Answer is that "lower" is a relative term. The short answer to the examiner's position is, So what? It has long been held that the use of relative terms in a patent claim does not per se give rise to a rejection under 35 U.S.C. § 112, second paragraph. In re Mattison, 509 F.2d 563,

564-65, 184 USPQ 484, 486 (CCPA 1975). Again, it will suffice for us to point out that the examiner has failed to present a reasoned, fact supported explanation why one skilled in the art would not be able to reasonably ascertain the metes and bounds of the term "lower alkanol."

The rejections under 35 U.S.C. § 112, first and second paragraphs, are reversed.

New Grounds of Rejection Under 37 CFR § 1.196(b)

Under the provisions of 37 CFR § 1.196(b), we make the following new grounds of rejection.

1. Obviousness-type double patenting.

Claims 2, 5 through 7, and 9 through 15 are rejected under the judicially created doctrine of obviousness-type double patenting on the basis of the claims of the '654 patent.

The claims of the '654 patent correspond to those pending in this application with the exception that the patented claims are limited to the presence of ethanol while the claims pending in this application require the presence of lower alkanols. Since ethanol is a lower alkanol, it should be beyond dispute that the claims in this application are an obvious variation of the claims of the '654 patent.

We note that appellants understood that an obviousness-type double patenting issue was raised when these claims were presented in immediate parent application 07/638,944 in that a terminal disclaimer was submitted with that application. However, terminal disclaimers do not carry forward to subsequent continuing applications. As the record in this application now stands, an appropriate terminal disclaimer is not of record. But see, the statement under 37 CFR § 1.196(c) set forth below.

2. Claim 7.

Claim 7 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.

While claim 7 refers to the lower alkanol required by claim 15, the result required in claim 7 is measured in terms of ethanol activity, not lower alkanol activity. Thus, claim 7 is indefinite on its face.

Appellants recognized this and attempted to amend claim 7 to obviate this error in an amendment filed with the Appeal Brief filed March 29, 1993. That amendment was not entered by the examiner. Thus, as of this date, the examiner has not allowed appellants to correct this error. Again, see the statement under 37 CFR § 1.196(c) below.

Statements Under 37 CFR § 1.196(c)

Under the provisions of this rule, we make the following two statements. First, if appellants file an appropriate terminal disclaimer in the time period set forth below, the



obviousness-type double patenting rejection would be obviated. Second, if the amendment to claim 7 filed March 29, 1993, is now approved for entry by the examiner, the new ground of rejection we have made of claim 7 under 35 U.S.C. § 112, second paragraph, would be obviated.

#### Time Period for Response

This opinion contains a new ground of rejection pursuant to 37 CFR § 1.196(b) (amended effective Dec. 1, 1997, by final rule notice, 62 Fed. Reg. 53,131, 53,197 (Oct. 10, 1997), 1203 Off. Gaz. Pat. & Trademark Office 63, 122 (Oct. 21, 1997)). 37 CFR § 1.196(b) provides that, "A new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that appellants, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of proceedings (§ 1.197(c)) as to the rejected claims:

(1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .

(2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

37 CFR § 1.196(c) provides:

Should the decision of the Board of Patent Appeals and Interferences include an explicit statement that a claim may be allowed in amended form, appellant shall have the right to amend in conformity with such statement which shall be binding upon the examiner in the absence of new references or grounds of rejection.

A statement pursuant to 37 CFR § 1.196(c) has been made in this decision. A time period in which appellants may file an amendment for the purpose stated in

§ 1.196(c) is hereby set to expire TWO MONTHS FROM THE DATE OF THIS DECISION.

No time period for taking subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

REVERSED - 37 CFR § 1.196(b) & (c)

Sherman D. Winters  
Administrative Patent Judge

William F. Smith  
Administrative Patent Judge

)  
)  
)  
)  
) BOARD OF PATENT  
) APPEALS AND  
) INTERFERENCES  
)  
)  
)

Appeal No. 94-2894  
Application 07/725,222

Fred E. McKelvey, Senior                    )  
Administrative Patent Judge                )

Michael W. Glynn  
Novartis Corporation  
Patent Department  
59 Route 10  
East Hanover, NJ 07936-1080